REMARKS

Claims 1-4, 6-8 and 10-13 are all the claims pending in the application.

On page 2 of the Office Action, claims 1-4, 6-8, and 10 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the "Technical Paper" entitled "Technique Paper for Wet-Spinning Poly(L-lactic acid) and Poly(DL-lactic-co-glycolide) Monofilament Fibers."

Applicants respectfully submit herewith evidence, namely a copy of the Abstract of the cited reference from the publisher's website, which indicates that the reference was actually published on July 9, 2004, which is later in time than the February 12, 2004 U.S. filing date of the present application. Referring to the Abstract of the cited reference, the Abstract notes that the article should be cited as December 2003, but the Abstract expressly states that the reference was not published until July 9, 2004. Thus, although the reference may have been submitted earlier, the reference does not appear to have been made available to the public until July 9, 2004. See MPEP § 2128.

Therefore, the Technical Paper is not prior art.

Withdrawal of the § 103 obviousness rejection based on the Technical Paper is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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WASHINGTON OFFICE
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Tissue Engineering

Technique Paper for Wet-Spinning Poly(L-lactic acid) and Poly (DL-lactide-co-glycolide) Monofilament Fibers

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A simple and repeatable method is described for wet-spinning poly(L-lactic acid) (PLLA) and poly(DL-lactic-co-glycolic acid) (PLGA) monofilament fibers. These fibers are strong, elastic, and suitable for many applications, including use as tissue-engineering scaffolds. The PLLA wet-extruded fibers do not show additional strain-induced crystallization as a result of drawing the fibers during fabrication; however, there is an apparent increase in crystallinity late in the degradation process in saline at 37° C. We have measured the molecular weight degradation in saline at 37° C for fibers of both PLLA and PLGA.

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Changing solvent systems, polymer blends, and winding rates alters mechanical and morphological properties of these fibers for specific applications. The authors discuss a possible theoretical explanation for these observed changes due to changes in polymer concentration, solvent system, and coagulation bath properties. This wet-extrusion process is simple and inexpensive enough to be carried out in almost any laboratory interested in tissue engineering.

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Technical Report

Technique Paper for Wet-Spinning Poly(L-lactic acid) and Poly(DL-lactide-co-glycolide) Monofilament Fibers

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ABSTRACT

A simple and repeatable method is described for wet-spinning poly(L-lactic acid) (PLLA) and poly(DL-lactic-co-glycolic acid) (PLGA) monofilament fibers. These fibers are strong, elastic, and suitable for many applications, including use as tissue-engineering scaffolds. The PLLA wet-extruded fibers do not show additional strain-induced crystallization as a result of drawing the fibers during fabrication; however, there is an apparent increase in crystallinity late in the degradation process in saline at 37°C. We have measured the molecular weight degradation in saline at 37°C for fibers of both PLLA and PLGA. Changing solvent systems, polymer blends, and winding rates alters mechanical and morphological properties of these fibers for specific applications. The authors discuss a possible theoretical explanation for these observed changes due to changes in polymer concentration, solvent system, and coagulation bath properties. This wet-extrusion process is simple and inexpensive enough to be carried out in almost any laboratory interested in tissue engineering.

INTRODUCTION

POLY(L-LACTIC ACID) (PLLA) poly(glycolic acid) (PGA), and their copolymers and blends have been used as bioresorbable polymers in medical applications since the 1960s.[1] They have been used as dissolvable sutures,[2] in orthopedic applications,[3,4] and more recently have become important synthetic scaffoldings for tissue-engineering applications.[5–11] They were chosen because they have FDA approval in many applications, they were found to have good strength, were readily processed, and easy to obtain, purify, and use in bulk quantities.

The fiber format was nearly always obtained by conventional melt-extrusion techniques; however, because of the size and cost of melt-extrusion equipment, and the large amount of raw material required, it has not been well suited to bench-top, laboratory quantities. Therefore, we sought other processing methods to obtain similar fibers. This article describes simple, inexpensive, bench-top techniques for wet-spinning PLLA and poly(DL-lactide-co-glycolide) (PLGA) monofilament fibers suitable for scaffoldings for tissue-engineering applications. The concept of wet-spinning is not new; Kulkarni *et al.* wet-spun PLLA fibers as far back as 1966.[1] However, wet-spinning has generally produced fibers not as mechanically strong as fibers produced by melt-extruding, and therefore has not been investigated as thoroughly. Therefore, we felt that a technical report to teach the concepts

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